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Office of Vaccines Research and Review and Division of Viral Products

Tod Merkel, PhD

Associate Director of Research, OVRR

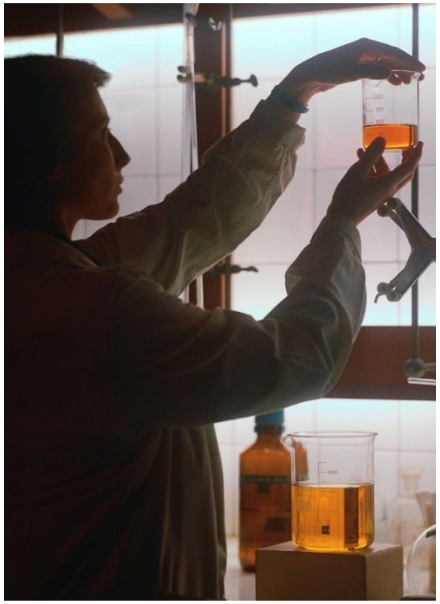
OVRR's Mission

To protect and enhance public health by assuring the availability of safe and effective vaccines, allergenic extracts, and other related products

OVRR Regulates

- Vaccines
- Allergenic products
- Live biotherapeutic products (probiotics, FMT)
- Phage

OVRR Core Activities



- **Review, evaluate, and take appropriate** actions on INDs, BLAs, amendments, and supplements for vaccines and related biological products and participation in inspections

- **Develop policies and procedures** governing the pre-market review of regulated products

- **Conduct research** related to the development, manufacture, and evaluation of vaccines and related products and to better understand pathological processes.

OVRR's Research Mission

- **The OVRR Research Program** is designed to complement and support the regulatory mission by focusing on issues related to the development of safe and effective products.

Importance of Research In Regulation of Vaccines and Related Products

Emphasis on Safety

- Products for mass use (often universal)
- Recipients are healthy individuals, often children

High level of Scrutiny by Public

- Regulatory decisions must be based on science
- Increasing number of anti-vaccine organization and groups

Keeping pace with technology

- New manufacturing technologies are rapidly evolving

Responding to Public Health Threats

- Antibiotic resistance
- Emerging agents

Generating results and placing them in the public domain

- Our research benefits not just individual companies but the entire industry sector, and therefore the American consumers

Recruiting and retaining expert scientist to support Review

OVRR's Research Is

Broad

Although we can't cover everything, we need to cover as much as possible within the scope of our responsibilities

Collaborative

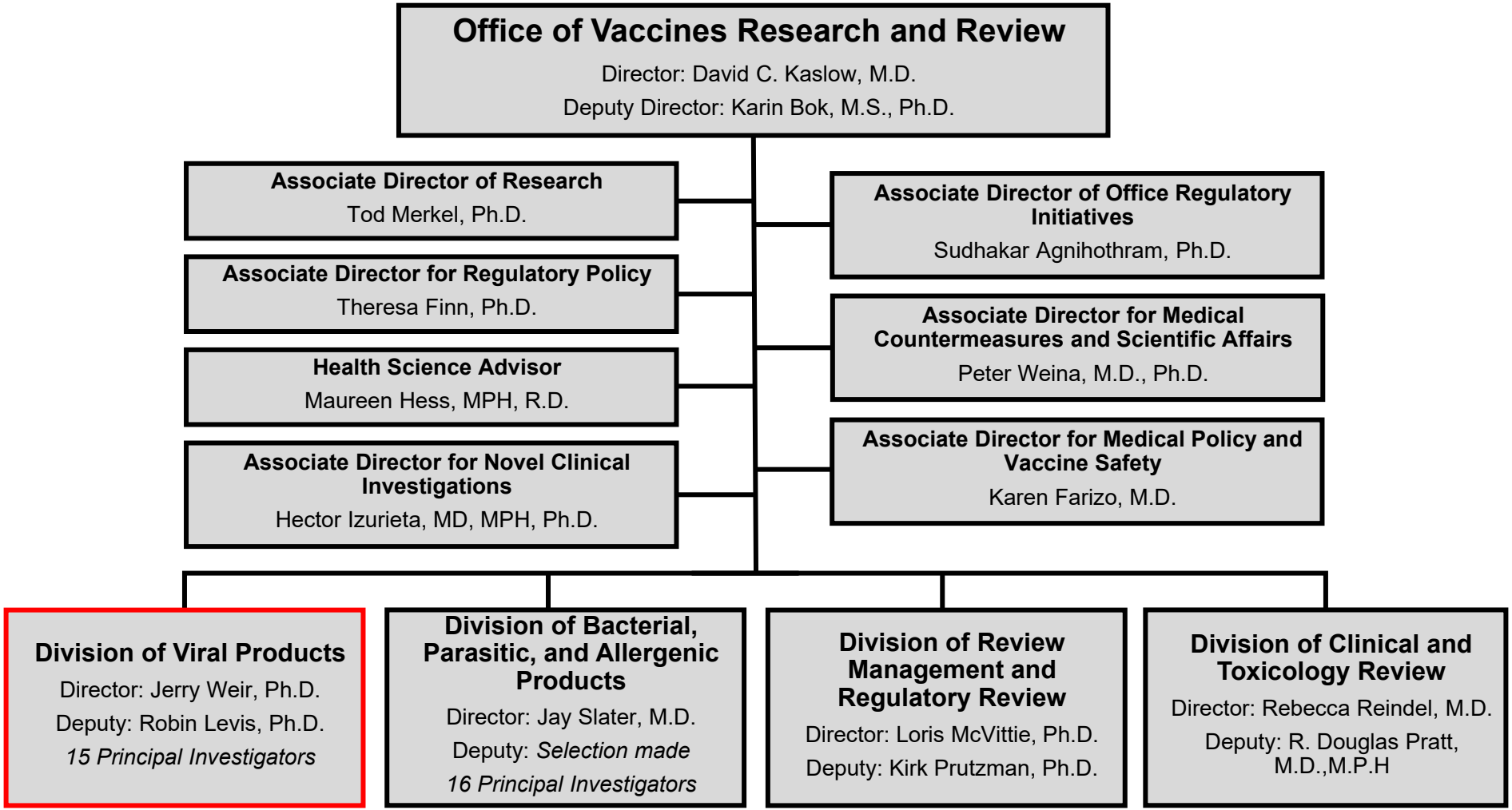
Collaboration with scientists around the country and the world allows us to leverage our investments in research

Excellent

- Our research is published and broadly cited and used
- Our research scientists are members of the broader scientific community, and many are well-known experts in their fields

Investigator-initiated and Flexible

This allows our researcher/reviewers to anticipate regulatory needs and proactively address important questions


Office of Vaccines Research and Review
Director: David C. Kaslow, M.D.
Deputy Director: Karin Bok, M.S., Ph.D.
Associate Director of Research
Tod Merkel, Ph.D.
Associate Director for Regulatory Policy
Theresa Finn, Ph.D.
Health Science Advisor
Maureen Hess, MPH, R.D.
Associate Director for Novel Clinical Investigations
Hector Izurieta, MD, MPH, Ph.D.
Associate Director of Office Regulatory Initiatives
Sudhakar Agnihothram, Ph.D.
Associate Director for Medical Countermeasures and Scientific Affairs
Peter Weina, M.D., Ph.D.
Associate Director for Medical Policy and Vaccine Safety
Karen Farizo, M.D.
Division of Viral Products
Director: Jerry Weir, Ph.D.
Deputy: Robin Levis, Ph.D.
15 Principal Investigators
Division of Bacterial, Parasitic, and Allergenic Products
Director: Jay Slater, M.D.
Deputy: Selection made
16 Principal Investigators
Division of Review Management and Regulatory Review
Director: Loris McVittie, Ph.D.
Deputy: Kirk Prutzman, Ph.D.
Division of Clinical and Toxicology Review
Director: Rebecca Reindel, M.D.
Deputy: R. Douglas Pratt, M.D.,M.P.H

DVP's Mission

- Regulate viral vaccines and related biological products, ensuring their safety and efficacy for human use

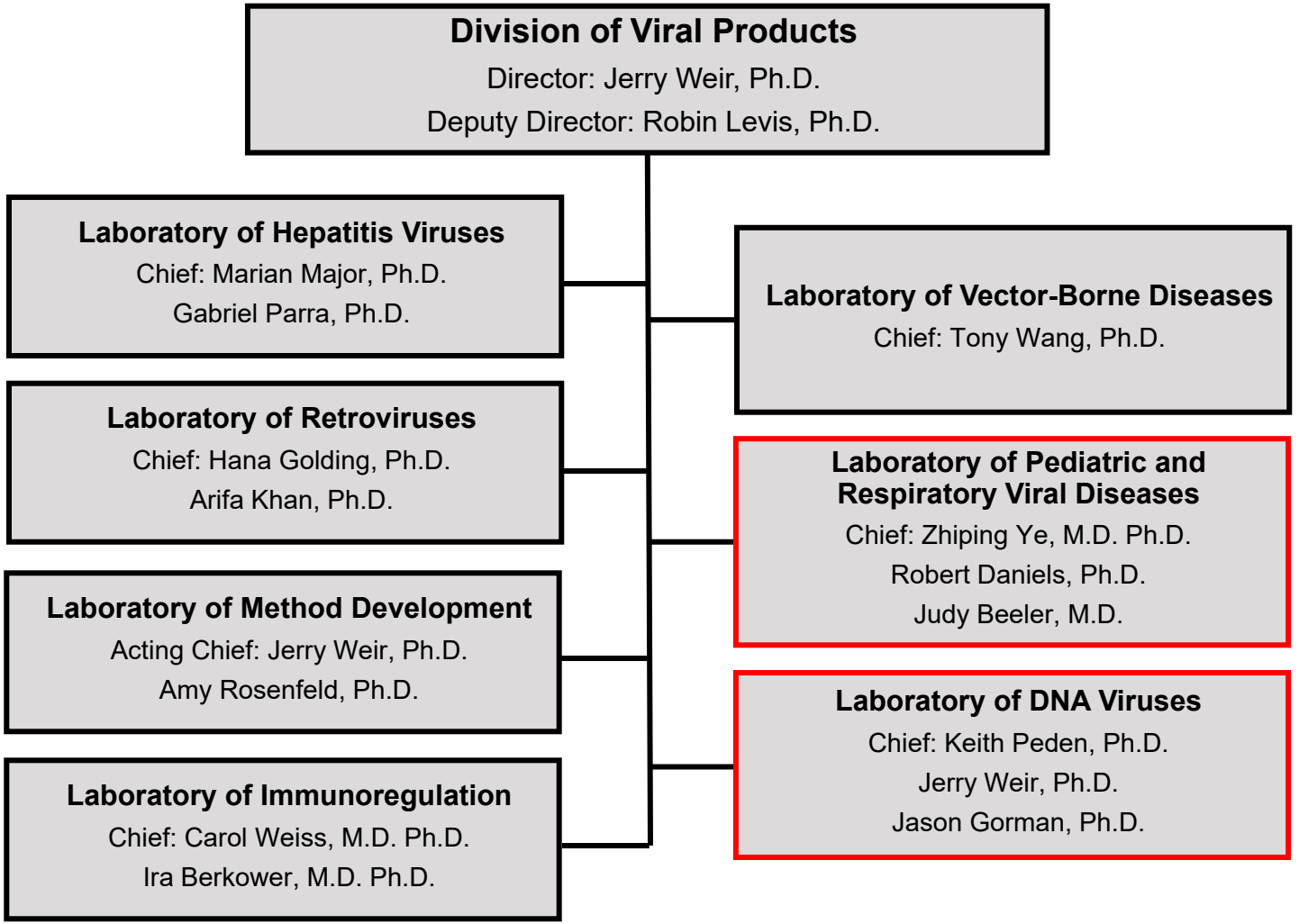
- Facilitate the development, evaluation, and licensure of new viral vaccines that positively impact the public health

DVP's Major Responsibilities

- Review of Investigational New Drug (IND) applications, Biologics License Applications (BLA), and other pre-marketing activities (e.g., pre-IND)
- Review of BLA supplements, lot release, and other post-marketing activities (e.g., Biological product deviations)
- Manufacturer inspections (pre- and post-licensure)
- Consultation with other public health agencies (e.g., WHO, CDC, NIBSC)
- Conduct research related to the development, manufacturing, evaluation, and testing of viral vaccines

Role of DVP's Research

- Research and laboratory activities complement the regulatory mission
- Address issues related to regulated viral vaccines
- Anticipate and address issues related to the development and evaluation of new viral vaccine products
  - General issues applicable to many products or product classes (e.g., cell substrate issues, improved test methods, etc.)
  - Specific product issues (correlates of protection necessary for efficacy evaluation, animal models necessary for animal rule implementation, etc.)


Division of Viral Products
Director: Jerry Weir, Ph.D.
Deputy Director: Robin Levis, Ph.D.
Laboratory of Hepatitis Viruses
Chief: Marian Major, Ph.D.
Gabriel Parra, Ph.D.
Laboratory of Retroviruses
Chief: Hana Golding, Ph.D.
Arifa Khan, Ph.D.
Laboratory of Method Development
Acting Chief: Jerry Weir, Ph.D.
Amy Rosenfeld, Ph.D.
Laboratory of Immunoregulation
Chief: Carol Weiss, M.D. Ph.D.
Ira Berkower, M.D. Ph.D.
Laboratory of Vector-Borne Diseases
Chief: Tony Wang, Ph.D.
Laboratory of Pediatric and Respiratory Viral Diseases
Chief: Zhiping Ye, M.D. Ph.D.
Robert Daniels, Ph.D.
Judy Beeler, M.D.
Laboratory of DNA Viruses
Chief: Keith Peden, Ph.D.
Jerry Weir, Ph.D.
Jason Gorman, Ph.D.

FDA U.S. FOOD & DRUG ADMINISTRATION

Thank you

Questions?